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| 10/783,807      | 02/20/2004  | Tetsuo Shibuya       | JP920030020US1      | 7767             |

7590 07/10/2008  
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| EXAMINER |
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SMITH, CAROLYN L

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1631

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07/10/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                                      |  |  |
|------------------------------|--------------------------------------|--|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/783,807 | <b>Applicant(s)</b><br>SHIBUYA, TETSUO |  |
|                              | <b>Examiner</b><br>Carolyn L. Smith  | <b>Art Unit</b><br>1631                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 28 March 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) 4-7, 10-12, 15, 16, 18 and 19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 8-9, 13-14, 17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Applicant's amendments and remarks, filed 3/28/08, are acknowledged. Amended claim 1, 8, 13, and 17 are acknowledged. Claims 4-7, 10-12, 15-16, and 18-19 remain withdrawn due to being drawn to non-elected Groups.

Applicant's arguments, filed 3/28/08, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from the previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 1-3, 8-9, 13-14, and 17 are herein under examination.

#### ***Claim Rejections - 35 USC § 112, Second paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 17 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 17 (lines 6-7) recites "generating complementary sequence data from a probe nucleotide sequence that may be bound to a target nucleotide sequence" which is confusing. It is unclear if the "complementary sequence data" is complementary to the probe or to the target

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nucleotide sequence. It is unclear if the limitation “that may be bound to a target nucleotide sequence” is referring to the “complementary sequence data” or to the “probe nucleotide sequence”. Clarification of this issue via clearer claim wording is requested. This rejection is maintained.

Applicant argues that the claim language “that may be bound to a target nucleotide” has been removed. This statement is found unpersuasive as the limitation is still present in instant claim 17.

### ***Claim Rejections – 35 USC §102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 8-9, 13-14, and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Fujimiya et al. (P/N 5,706,498). This rejection is maintained and reiterated for reasons of record.

Fujimiya et al. disclose a computer system, method, program, and computer readable medium for executable screening nucleotide sequences (abstract and Figures 2-4, col. 3, second and third paragraphs, col. 8, first 2 paragraphs; and col. 13, first paragraph), as stated in the preamble of instant claims 1, 8, 13, and 17. Fujimiya et al. disclose storing sequence data of genes including target sequence data and key sequence data which exhibit a high degree of

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similarity (abstract and title and Figure 2 and col. 1, third paragraph; col. 2, fourth paragraph; col. 9, last paragraph) for homology retrieval (col. 2, fourth paragraph) including key memory and target memory (Figure 2) which represent a target and a complementary sequence data storing units, as stated in instant claims 1, 8, 13, and 17. Fujimiya et al. disclose retrieval databases and analyzing and determining the final sequence of bases by extracting a portion of the gene probe bound to a chromosome (col. 2, third paragraph) which represents generating complementary sequence data from a probe sequence that may be bound to the target sequence and storing such data, as stated in instant claims 1, 8, 13, and 17. Fujimiya et al. disclose a dynamic operation unit for determining the degree of similarity between the target data and the key data by utilizing base sequence data of each (abstract), grouping homologous sequences, and retrieving the homologous gene sequence (col. 1, fifth paragraph and col. 2, second paragraph) using dynamic programming by summing up points from the starting point of the operation for determining the locally optimal path (i.e. number of adjustments) solution as a whole using insertions, deletions, and substitutions for the first to last combinations of data (col. 2, last paragraph, col. 3, third and fourth paragraphs, and Figures 7a and 7b), altering target data one after another with respect to key data and determining degree of similarity by entering the base sequence data one after another of the target data and storing the maximal sum value occurring at the time of operation (col. 9, lines 21-67; col. 12, lines 32-39; col. 13, lines 1-22), as well as displaying maximal values of each target data in the order of higher degrees of similarity (col. 23, third paragraph) and probe binding evaluation (col. 2, second and third paragraphs) which represents an evaluation processing unit for evaluating a binding possibility of the target nucleotide sequence data to the probe sequence via determination of whether the complementary

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sequence data is similar to a subsequence of the target nucleotide sequence data in descending order of edit distance of binding precision, wherein edit distance is the number of times nucleotides of the subsequence are required to be adjusted to generate the complementary (key) sequence data, as stated in instant claims 1, 8, 13, and 17. Fujimiya et al. disclose preparing a gene probe on the basis of the gene having high retrieval accuracy and analyzing and determining the binding possibility of the probe on the involved gene on a chromosome (col. 2, second and third paragraphs), as stated in instant claims 1, 8, 13, and 17. Fujimiya et al. disclose a database and retrieving of sequence data using a sequence similar thereto (col. 1, first paragraph) and probe binding analysis and determination (col. 2, second and third paragraphs) and evaluation processing for a user (col. 23, third paragraph) which represents a storage unit for storing the evaluation result for the user in determining probe binding effectiveness and reliability, as stated in instant claims 1, 8, 13, and 17. Fujimiya et al. disclose using 10 base elements in the sequence data (col. 4, second paragraph) as well as using partial sequences (col. 4, third paragraph). Fujimiya et al. disclose a system including storage of data and a similarity degree whereby the score value at the initial condition is set to zero given the condition in which the maximal length  $\alpha$  of the sequence is inserted or lost at one time involving partial sequences as well as setting  $\alpha$  to 1 to get a maximal score value (col. 4, last paragraph, and col. 5, and abstract) and performing an operation until reaching a predetermined length of the key or target data and acquiring the maximal value of the sum values with direction selection data (col. 10, line 57 to col. 11, line 43) as well as a constant value to compare sum values (col. 12, lines 1-17) which represents a maximum edit distance storing unit, as stated in instant claims 2, 8, 13, and 17. Fujimiya et al. disclose setting a maximal value as a score of the node and applied to the

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origin and subsequent lattice points until finishing the basic operation and determining the wholly optimal disposition of the three routes (col. 5, last paragraph to col. 6, second paragraph) which represents determining a termination point and a termination-determining unit determining evaluation carried out over maximal (acceptable) edit distance, as stated in instant claims 3, 9, and 14. Fujimiya et al. disclose a score value of each route is added, including target-side data and key-side data, as well as outputting sequence data and displaying maximal values and direction selection data (path) (col. 3, third to col. 4, first paragraph; col. 5, second to last paragraph to col. 6, second paragraph; col. 10; col. 11, lines 44-48; col. 20, first paragraph; col. 23, third paragraph; and Figures 7 and 8) which represents reading out each target nucleotide sequence data, complementary sequence data, and each maximum acceptable edit distance, as stated in instant claims 8, 13, and 17. Fujimiya et al. disclose the wholly optimal disposition is determined after the basic operations have been made (col. 6, second paragraph and Figures 3-4 and 6) and an interruption signal issued to the microprocessor when the operation is terminated (col. 24, last paragraph) which represents generating a termination signal in response to the determination result, as stated in instant claims 9 and 14. Fujimiya et al. disclose using the ability to apply dynamic programming to a local region having approximately 16 bases (col. 7, fourth paragraph).

Thus, Fujimiya et al. anticipate the instant invention.

Applicant requests that the Examiner refrains from grouping claim language of the claims together when presenting the rejection and prefers a claim by claim presentation. It is noted that

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the rejection is presented in a standard format where all of the limitations are addressed.

Applicant is free to present arguments in a claim by claim basis.

Applicant summarizes Fujimiya et al. and argues that retrieving genes from a database does not anticipate screening nucleotide sequences. This statement is found unpersuasive as assessing a degree of similarity with respect to key data and homology retrieval of a gene sequence to be extracted from target data (i.e. col. 8, first paragraph) represents screening nucleotide sequences given its broadest and reasonable interpretation.

Applicant argues that the target data and the key data disclosed by Fujimiya et al. does not anticipate target and complementary sequence data as recited in the instant claims, because Fujimiya does not disclose generating complementary sequence data from a probe nucleotide sequence. This statement is found unpersuasive as "generating complementary sequence data from a probe nucleotide sequence" can be interpreted several ways. In one interpretation, the complementary sequence data is *any* data representing a sequence that is complementary to a probe. In another interpretation, a probe is defined as being a complementary sequence (i.e. a probe is complementary to a target). In the latter interpretation, the probe itself, or any data relating to it, reasonably represents complementary sequence data. Applicant summarizes Fujimiya et al. and argues that retrieval databases and analyzing and determining the final bases by extracting a portion of the gene probe bound to a chromosome does not teach generating complementary sequence. This statement is found unpersuasive as "complementary sequence data" has been interpreted broadly and reasonably, as described above.

Applicant argues that Fujimiya et al. fail to teach evaluating a binding possibility of the target nucleotide sequence data to the probe nucleotide sequence data via determination of

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whether the complementary sequence data of the probe nucleotide sequence is similar to a subsequence of the target nucleotide sequence data. This statement is found unpersuasive based on the broad and reasonable interpretation of “complementary sequence data” as already described above. Also, determining the degree of similarity is an evaluation of binding possibility.

Applicant again argues that Fujimiya et al. do not disclose complementary sequence data which has already been found unpersuasive as discussed above.

Applicant argues that Fujimiya et al. do not disclose an evaluation is performed in descending order of edit distance. This statement is found unpersuasive as Fujimiya et al. disclose a dynamic operation unit for determining the degree of similarity between the target data and the key data by utilizing base sequence data of each (abstract), grouping homologous sequences, and retrieving the homologous gene sequence (col. 1, fifth paragraph and col. 2, second paragraph) using dynamic programming by summing up points from the starting point of the operation for determining the locally optimal path (i.e. number of adjustments) solution as a whole using insertions, deletions, and substitutions for the first to last combinations of data (col. 2, last paragraph, col. 3, third and fourth paragraphs, and Figures 7a and 7b), altering target data one after another with respect to key data and determining degree of similarity by entering the base sequence data one after another of the target data and storing the maximal sum value occurring at the time of operation (col. 9, lines 21-67; col. 12, lines 32-39; col. 13, lines 1-22), as well as displaying maximal values of each target data in the order of higher degrees of similarity (col. 23, third paragraph) and probe binding evaluation (col. 2, second and third paragraphs).

Applicant argues that Fujimiya et al. is concerned with finding target data that best matches the

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key data and searches for the best match first as opposed to the worst match first (e.g., descending order of edit distance). This statement is found unpersuasive for several reasons. First, descending order of edit distance can reasonably be interpreted to be an edit distance going in a downward direction (as seen in Figures 7a and 7b). Second, the interpretation of the limitation "descending order of edit distance" can vary depending on how ones defines "descending". If "descending" order is a "worsening" order, then one starts with 'the minimum number of operations to transform one string to another' (optimal edit distance) and works toward 'the maximum number of operations' in which case the best match is being searched for first, as Applicant claims Fujimiya et al. is doing. As described in Fujimiya et al. (col. 2, last paragraph), one starts small, adds on, which can increase changes (i.e. number of operations). As described in Fujimiya et al. (col. 9, lines 21-67), target data is altered one after another to determine similarity to the key data and acquiring the sum data at each target data occurring at the operation. This goes from minimum to maximum number of operations (i.e. descending order of edit distance).

Applicant argues that Fujimiya et al. is not concerned with determining binding effectiveness and reliability of a probe to a target, but rather retrieves genes from a gene database using a sequence as a key. This statement is found unpersuasive as Fujimiya et al. disclose a database and retrieving of sequence data using a sequence similar thereto (col. 1, first paragraph) and probe binding analysis and determination (col. 2, second and third paragraphs) and evaluation processing for a user (col. 23, third paragraph) which represents a determining probe binding effectiveness and reliability.

Applicant argues that Fujimiya et al. fail to anticipate independent claims 1, 8, 13, and 17 and their dependent claims 2, 3, 9, and 14. This statement is found unpersuasive as all of these claims are anticipated by Fujimiya et al. as described above.

Applicant's arguments are deemed unpersuasive for the reasons given above.

### ***Conclusion***

No claim is allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The

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faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The Central Fax Center number for official correspondence is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. If you have questions on access to the Private PAIR system, please contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, please call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (571) 272-0721. The examiner can normally be reached Monday through Thursday from 8 A.M. to 6:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran, can be reached on (571) 272-0720.

July 1, 2008

/Carolyn Smith/  
Primary Examiner  
AU 1631